

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

FILED
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DEAN LANGFORD and
NANCY LANGFORD,
husband and wife,

Case No.: 03-12245-RCL

U.S. DISTRICT COURT
DISTRICT OF MASS.

Plaintiffs,

v.

ZIMMER, INC. and
ZIMMER HOLDINGS, INC.,

Defendants.

JURY TRIAL DEMANDED

ANSWER OF ZIMMER HOLDINGS, INC. TO FIRST AMENDED COMPLAINT

For its Answer to Plaintiffs' First Amended First Amended Complaint, Defendant Zimmer Holdings, Inc. ("ZHI") denies each and every allegation, matter and thing alleged except as may be hereinafter admitted, qualified or explained, and states and alleges as follows:

PARTIES

1. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of Plaintiffs' First Amended First Amended Complaint, and therefore denies same.

2. ZHI admits the allegations contained in paragraph 2 of Plaintiffs' First Amended Complaint.

3. ZHI admits the allegations contained in paragraph 3 of Plaintiffs' First Amended Complaint.

JURISDICTION

4. ZHI admits that Zimmer, Inc. and Zimmer Holdings, Inc. are corporations incorporated under the laws of Delaware with headquarters in Warsaw, Indiana and that the matter in controversy exceeds \$75,000. The remainder of the allegations contained in paragraph 4 of Plaintiffs' First Amended Complaint state legal conclusions to which no response is required.

GENERAL BACKGROUND

5. ZHI denies the allegations contained in paragraph 5 of Plaintiffs' First Amended Complaint.

6. ZHI admits that Zimmer, Inc. was purchased by Bristol-Myers Company in 1972. ZHI denies the remaining allegations contained in paragraph 6 of Plaintiffs' First Amended Complaint.

7. ZHI admits that Zimmer Holdings, Inc. was created in January 2001. ZHI denies the remaining allegations contained in paragraph 7 of Plaintiffs' First Amended Complaint.

8. On information and belief, ZHI admits that from time to time Zimmer, Inc. has sold products in the United States and in other countries. ZHI denies the remaining allegations contained in paragraph 8 of Plaintiffs' First Amended Complaint.

9. ZHI admits that from time to time Zimmer, Inc. has made public statements. ZHI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 9 of Plaintiffs' First Amended Complaint, and therefore denies same.

10. On information and belief, ZHI admits that Zimmer, Inc. sells products for use in the hip. On information and belief, ZHI denies the remaining allegations contained in paragraph 10 of Plaintiffs' First Amended Complaint.

11. On information and belief, ZHI denies the allegations contained in Paragraph 11 of Plaintiffs' First Amended Complaint.

12. On information and belief, ZHI admits there are different methods of fixation for a femoral component. On information and belief, ZHI denies the remaining allegations contained in Paragraph 12 of Plaintiffs' First Amended Complaint.

13. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 13 of Plaintiffs' First Amended Complaint, and therefore denies same.

14. On information and belief, ZHI denies the allegations contained in paragraph 14 of Plaintiffs' First Amended Complaint.

15. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 15 of Plaintiffs' First Amended Complaint, and therefore denies same.

16. On information and belief, ZHI admits that Zimmer, Inc. was assigned United States Patent 4,795,472. ZHI denies the remaining allegations contained in paragraph 16 of Plaintiffs' First Amended Complaint.

17. On information and belief, ZHI denies the allegations contained in paragraph 17 of Plaintiffs' First Amended Complaint.

18. On information and belief, ZHI denies the allegations contained in paragraph 18 of Plaintiffs' First Amended Complaint.

19. On information and belief, ZHI denies the allegations contained in paragraph 19 of Plaintiffs' First Amended Complaint.

20. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 20 of Plaintiffs' First Amended Complaint, and therefore denies same.

21. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 21 of Plaintiffs' First Amended Complaint, and therefore denies same.

22. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 22 of Plaintiffs' First Amended Complaint, and therefore denies same.

23. On information and belief, ZHI denies the allegations contained in paragraph 23 of Plaintiffs' First Amended Complaint.

24. On information and belief, ZHI denies the allegations contained in paragraph 24 of Plaintiffs' First Amended Complaint.

THE ZIMMER CENTRALIGN

25. On information and belief, ZHI admits that Zimmer, Inc. introduced the Centralign in 1992. On information and belief, ZHI denies the remaining allegations contained in paragraph 25 of Plaintiffs' First Amended Complaint.

26. ZHI is without knowledge or information sufficient to form a belief as to whether Mr. Langford received a Centralign prosthesis, and therefore denies same. On information and belief, ZHI denies the remaining allegations contained in paragraph 26 of Plaintiffs' First Amended Complaint.

27. ZHI denies the allegations contained in paragraph 27 of Plaintiffs' First Amended Complaint.

28. On information and belief, ZHI denies the allegations contained in paragraph 28 of Plaintiffs' First Amended Complaint.

29. On information and belief, ZHI denies the allegations contained in paragraph 29 of Plaintiffs' First Amended Complaint.

30. On information and belief, ZHI denies the allegations contained in paragraph 30 of Plaintiffs' First Amended Complaint.

31. On information and belief, ZHI denies the allegations contained in paragraph 31 of Plaintiffs' First Amended Complaint.

32. On information and belief, ZHI denies the allegations contained in paragraph 32 of Plaintiffs' First Amended Complaint.

33. On information and belief, ZHI denies the allegations contained in paragraph 33 of Plaintiffs' First Amended Complaint.

PLAINTIFF'S INJURY

34. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 34 of Plaintiffs' First Amended Complaint, and therefore denies same.

35. On information and belief, ZHI denies the allegations contained in paragraph 35 of Plaintiffs' First Amended Complaint.

36. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 36 of Plaintiffs' First Amended Complaint, and therefore denies same.

37. ZHI denies the allegations contained in paragraph 37 of Plaintiffs' First Amended Complaint.

COUNT I
Negligence

38. ZHI incorporates its responses to paragraphs 1 through 37 of Plaintiffs' First Amended Complaint as if fully set forth herein.

39. The allegations contained in paragraph 39 of Plaintiffs' First Amended Complaint state a legal conclusion to which no response is required. To the extent a response is required, ZHI admits that when Zimmer, Inc. manufactures and sells products certain duties are imposed on Zimmer, Inc. ZHI is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 39 of Plaintiffs' First Amended Complaint, and therefore denies same.

40. ZHI denies the allegations contained in paragraph 40 of Plaintiffs' First Amended Complaint.

41. ZHI denies the allegations contained in paragraph 41 of Plaintiffs' First Amended Complaint, including subparagraphs a through g.

42. ZHI denies the allegations contained in paragraph 42 of Plaintiffs' First Amended Complaint.

43. ZHI denies the allegations contained in paragraph 43 of Plaintiffs' First Amended Complaint.

44. ZHI denies the allegations contained in paragraph 44 of Plaintiffs' First Amended Complaint.

COUNT II
Strict Product Liability (Failure to Warn)

45. ZHI incorporates its responses to paragraphs 1 through 44 of Plaintiffs' First Amended Complaint as if fully set forth herein.

46. On information and belief, ZHI admits that Zimmer, Inc. manufactured and sold Centralign hip implants. On information and belief, ZHI denies the remaining allegations contained in paragraph 46 of Plaintiffs' First Amended Complaint.

47. ZHI denies the allegations contained in paragraph 47 of Plaintiffs' First Amended Complaint.

48. ZHI denies the allegations contained in paragraph 48 of Plaintiffs' First Amended Complaint.

49. ZHI denies the allegations contained in paragraph 49 of Plaintiffs' First Amended Complaint.

50. ZHI denies the allegations contained in paragraph 50 of Plaintiffs' First Amended Complaint.

COUNT III
Strict Product Liability (Defective Design, Manufacture and Testing)

51. ZHI incorporates its responses to paragraphs 1 through 50 of Plaintiffs' First Amended Complaint as if fully set forth herein.

52. ZHI denies the allegations contained in paragraph 52 of Plaintiffs' First Amended Complaint, including subparagraphs a through h.

53. ZHI denies the allegations contained in paragraph 53 of Plaintiffs' First Amended Complaint.

COUNT IV
Breach of Express Warranties

54. ZHI incorporates its responses to paragraphs 1 through 53 of Plaintiffs' First Amended Complaint as if fully set forth herein.

55. ZHI denies the allegations contained in paragraph 55 of Plaintiffs' First Amended Complaint.

56. ZHI denies the allegations contained in paragraph 56 of Plaintiffs' First Amended Complaint.

COUNT V
Breach of Implied Warranties

57. ZHI incorporates its responses to paragraphs 1 through 56 of Plaintiffs' First Amended Complaint as if fully set forth herein.

58. ZHI denies the allegations contained in paragraph 58 of Plaintiffs' First Amended Complaint.

59. ZHI denies the allegations contained in paragraph 59 of Plaintiffs' First Amended Complaint.

COUNT VI
Deceptive Acts and Practices

60. ZHI incorporates its responses to paragraphs 1 through 59 of Plaintiffs' First Amended Complaint as if fully set forth herein.

61. ZHI denies the allegations contained in paragraph 61 of Plaintiffs' First Amended Complaint.

62. ZHI denies the allegations contained in paragraph 62 of Plaintiffs' First Amended Complaint, including subparagraphs a through h.

63. ZHI denies the allegations contained in paragraph 63 of Plaintiffs' First Amended Complaint.

64. ZHI denies the allegations contained in paragraph 64 of Plaintiffs' First Amended Complaint.

COUNT VII
Loss of Consortium

65. ZHI incorporates its responses to paragraphs 1 through 64 of Plaintiffs' First Amended Complaint as if fully set forth herein.

66. ZHI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 66 of Plaintiffs' First Amended Complaint, and therefore denies same.

67. ZHI denies the allegations contained in paragraph 67 of Plaintiffs' First Amended Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

If Plaintiffs sustained injuries or incurred expenses as alleged, the same may have been caused in whole or in part by the conduct of one or more persons or entities for whose conduct ZHI was not responsible and with whom ZHI had no legal connection or no duty to control.

SECOND AFFIRMATIVE DEFENSE

If Plaintiffs sustained injuries or incurred expenses as alleged, the same were not due to, or caused by, the fault, lack of care, negligence, strict liability, or any other breach of duty on the part of ZHI.

THIRD AFFIRMATIVE DEFENSE

If Plaintiffs sustained injuries or incurred expenses as alleged, the same may have been the result of intervening and/or superseding causes, and not as a result of the acts or omissions of ZHI.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs cannot recover under the First Amended Complaint because ZHI complied with all applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States, the State of Massachusetts, and/or by an agency of the United States or Massachusetts.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by virtue of the intervention of a learned intermediary or intermediaries to whom any duty to warn was discharged.

SIXTH AFFIRMATIVE DEFENSE

ZHI's warnings and instructions were at all times in conformity with the generally recognized state of scientific and technological knowledge at the time such warnings and instructions were issued.

SEVENTH AFFIRMATIVE DEFENSE

At all times material to the First Amended Complaint, the product at issue was accompanied by reasonable instructions and warnings to the physician and other health-care providers.

EIGHTH AFFIRMATIVE DEFENSE

The products at issue were supplied, if at all, to a sophisticated user, and therefore, ZHI is not legally responsible for either the acts or omissions of the sophisticated user or misinformation or lack of information provided to the Plaintiffs by others.

NINTH AFFIRMATIVE DEFENSE

Upon information and belief, if Plaintiffs sustained injuries or incurred expenses as alleged, the same may have been caused by misuse of the product, and such misuse could not have been reasonably expected.

TENTH AFFIRMATIVE DEFENSE

Upon information and belief, if Plaintiffs sustained injuries or incurred expenses as alleged, the same may have been caused by modification or alteration of the product, and such modification or alteration was not reasonably expected.

ELEVENTH AFFIRMATIVE DEFENSE

The product at issue is a prescription medical product that is neither defective nor unreasonably dangerous. At all times material to this incident, the product was reasonably safe and fit for its intended use and the warnings and instructions accompanying it at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate.

TWELFTH AFFIRMATIVE DEFENSE

The product at issue is neither defective nor unreasonably dangerous because it is a product which falls within the "comment k exception" to strict tort liability defined in Section 402A of the Restatement (Second) of Torts.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs are time-barred by virtue of the expiration of the applicable statute of limitations or applicable statute of repose, or the Equitable Doctrine of Laches.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' injuries, if any, were caused by pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses of the Plaintiff.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs have failed to state a claim upon which relief can be granted.

SIXTEENTH AFFIRMATIVE DEFENSE

In the event that Plaintiffs recover a verdict for personal injury, the amount of such recovery should be reduced by any payment that Plaintiffs received under the medical payment provisions, or any other provision, of any policy of insurance.

SEVENTEENTH AFFIRMATIVE DEFENSE

In the event Plaintiffs recover a verdict for judgment against ZHI, then that verdict or judgment must be reduced by those amounts which have been, or will, with reasonable certainty, replace or indemnify Plaintiffs, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, social security, worker's compensation or employee benefit program.

EIGHTEENTH AFFIRMATIVE DEFENSE

That at all times mentioned in Plaintiffs' First Amended Complaint on file herein, the Plaintiffs assumed the risk; i.e. the Plaintiffs had actual knowledge and full appreciation of the probabilities and possibilities of risks attendant upon their actions and course of action, and voluntarily and without compulsion or coercion, encountered and assumed any and all such attendant risks.

NINETEENTH AFFIRMATIVE DEFENSE

The damages alleged by Plaintiffs resulted from the negligent acts or omissions of the Plaintiffs which negligence was greater than that of ZHI. Accordingly, the Plaintiffs are barred from recovery from ZHI, in whole or in part, in accordance with M.G.L. c.231 sec. 85.

TWENTIETH AFFIRMATIVE DEFENSE

ZHI alleges that on balance, in light of the relevant factors, ZHI exercised the degree of care in its plan or design so as to avoid any unreasonable risk of harm to anyone who was likely to be exposed to the dangers when the product was used in the manner for which the product was intended as well as an unintended yet reasonably foreseeable use.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs failed to notify ZHI of the alleged deficiencies in the product within a reasonable time after the discovery of the alleged deficiencies.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Any alleged warranty was disclaimed.

TWENTY-THIRD AFFIRMATIVE DEFENSE

The First Amended Complaint fails to state a cause of action against ZHI because the federal government has preempted the field of law applicable to the product alleged to have caused Plaintiffs' injuries. The granting of the relief prayed for in the First Amended Complaint would impede, impair, frustrate or burden the effectiveness of federal law regulating such field of law and would violate the Supremacy Clause (Art. VI, Clause 2) of the United States Constitution.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

ZHI expressly reserves the right to file further pleadings and to assert additional defenses as the proof develops.

DEMAND FOR JURY TRIAL

ZHI, pursuant to Rule 38 of the Federal Rules of Civil Procedure, respectfully demands a trial by jury on all issues so triable.

Respectfully submitted,

DATED: June 9, 2004

Zimmer Holdings, Inc.

By: 

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CERTIFICATE OF SERVICE

The undersigned certifies that on the 9th day of June, 2004, a copy of the foregoing ANSWER OF ZIMMER HOLDINGS, INC. TO FIRST AMENDED COMPLAINT was served on the following counsel of record by first-class mail, postage prepaid:

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